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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 10 1998

WARNING LETTER

Ref: OC: I-1790

Mr. Hsu Chao-Fa
Sales Manager
Giant Gun Electrical Optical Co.
13, Lane 81 Sec 2, Tan
Fu Road, Tan Tzu-Village
Taichung Hsien, R.O.C.

Mr. Tim Hofer
New Buffalo Corp.
18067 Edison Ave.
Chesterfield, Missouri 63005

Gentlemen:

This is to inform you of noncompliance with the Federal laser performance standard of models TP09 and TP11 laser pointers produced by your firm and intended for distribution in the United States. Units of these models were selected for field test from a shipment of 200 units consigned to New Buffalo Corporation, 18067 Edison Ave., Chesterfield, Missouri 63005.

The following items of noncompliance are applicable to the model LP09 and were observed:

1. 21 CFR 1040.10(c) and 1040.10(d): Classification of laser products. The model TP09 was misclassified in that the radiation output of the unit tested exceeded the Class IIIa limit of 5 mW. As a result, this model is Class IIIb and fails to comply with the requirements of the standard applicable to Class IIIb laser products.

2. 21 CFR 1040.11(b): Alignment laser products. Laser pointers are surveying, leveling and alignment laser products and are limited to a maximum output of 5mW. The TP09 was noncompliant with respect to this requirement.

The following items of noncompliance are applicable to both the TP09 and the TP11:

1. 21 CFR 1010.2: Certification. Labels certifying that the products comply with the standard were not affixed to the products as required nor included in the user information.

2. 21 CFR 1010.3: Identification. Labels containing the information specified in this regulation were not affixed to the products nor included in the user information.

3. 21 CFR 1040.10(g): Labeling requirements. The required warning logotype label was not affixed to the products as required by 21 CFR 1040.10(g) (10). Inclusion of this label in the package with instructions for the purchaser to affix the label to the product is not acceptable. The label must be permanently affixed to the products by the manufacturer at the time of certification, and the products must be in full compliance with the standard at the time the products are presented for entry into U.S. Commerce.

4. 21 CFR 1040.10(g)(5): Aperture label. Aperture labels were not affixed to the products as required.

5. 21 CFR 1040.10(h): User information: The warning logotype reproduced in the "User Instructions" was incorrect. The logotype shown identified the product as being a Class II laser product with a maximum output of less than 1mW when the intended class of the product was Class IIIa with an output of less than 5mW. Further, additional information required in Position 2 of the label was lacking, and the location(s) on the product of the required warning labels were not shown in these instructions as required by 21 CFR 1040.10(h)(iii).

We understand that these products have been refused entry into the United States and therefore will not require the submission of notification or a corrective action plan (CAP) for that particular shipment.

For any similar noncompliant laser products that may have been imported into the United States, you are hereby advised that section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports.

Failure to respond to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The Food and Drug Administration (FDA) is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum penalty of $300,000 without further notification by the FDA. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

You must respond in writing within 15 days of receipt of this letter under one of the options listed below. In your response you must also provide the number of the referenced products which have been produced and the number of such products that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation - You may submit your views and evidence to establish that the alleged failures to comply do not exist.

2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).

3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.

    a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.

    b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

Based on the noncompliances cited above, it is clear that Giant Gun Electrical Optical Co. has failed to establish and maintain a quality assurance and testing program that assures compliance of your laser products with the standard. Therefore, by this letter, the Center for Devices and Radiological Health (CDRH), Food and Drug Administration disapproves the quality control and testing program for all laser products produced by or for Giant Gun Electrical Optical Co. This action is taken under authority of the United States (U.S.) Federal Food, Drug and Cosmetic act, Chapter V. Subchapter C - Electronic Products Radiation Control (hereafter referred to as "the Act").

This disapproval means that your firm is prohibited by Sections 534(h) and 538 of the Act from:

1. Certifying the electronic products manufactured under the disapproved testing program;

2. Introducing or importing products into United States (U.S.) commerce which bear false and misleading certification, that is, products certified under the testing program which has been disapproved, and

3. Introducing or importing into U.S. commerce any product which does not have a certification label permanently affixed to the product, as required by 21 CFR 1010.2.

Under Section 536(a) of the Act, the CDRH is required to refuse entry or importation into the U.S. of any electronic product if it appears that the product fails to comply with the applicable standards, or the manufacturer's testing program has been disapproved.

To resolve this matter, you must submit all the information required under 21 CFR 1002.10 so that the CDRH can determine that your companies are in compliance with the Act, that the subject products comply with the performance standard, and that the testing program is in accord with good manufacturing practices.

The CDRH will advise you whether your submittal is satisfactory.

You must submit your response to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. Should you have any questions regarding this letter, please contact Frank W. Mackison, Consumer Safety Officer, at 301-594-5654.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center For Devices and
Radiological Health